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10/069,773	06/05/2002	Frank Volke	31583-178427 RK	3754

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EXAMINER

METZMAIER, DANIEL S

ART UNIT	PAPER NUMBER
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1712

DATE MAILED: 09/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/069,773

Applicant(s)

VOLKE ET AL.

Examiner

Daniel S. Metzmaier

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 050603.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

Claims 1-5 are pending. The following papers have been entered. Notice of missing parts, PCT/DO/EO/905 mailed May 2, 2002; The Declaration and the Information Disclosure Statement (indicated in the PCT/DO/EO/903 form) filed June 5, 2002; Notice of Acceptance letter, PCT/DO/EO/903, mailed 16 July 2002; the preliminary amendment filed June 5, 2002 amending claim 5.

#### ***Priority***

1. Receipt is acknowledged of papers received in this national stage application from the International Bureau (PCT Rule 17.2(a)), submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

#### ***Specification***

2. The abstract of the disclosure is objected to because it does not provide specific examples for each of the surface-active agent, "such as sodium dioctylsulfosuccinate", and polysaccharide, "such as trehalose". Applicant is reminded of the proper content of an Abstract of the Disclosure.

In chemical patent abstracts for compounds or compositions, the general nature of the compound or composition should be given as well as its use, e.g., "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary.

Correction is required. See MPEP § 608.01(b).

3. The disclosure is objected to because of the following informalities: the term "trahalose" is misspelled on page 6, third full paragraph.

Appropriate correction is required.

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4. The use of the trademark Aerosol® OT has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

***Claim interpretation***

5. Claim 1 is directed to the use of a homogenized mixture as a coupling medium from traverse ultrasonic waves. Claim 2 recites method steps not set forth in claim 1 including applied and pressed. It is suggested applicants employ positive language such as, "applying a layer of the mixture between . . . " and "pressing said two surfaces together". The probe set forth in the claim must be capable of transmitting and receiving traverse ultrasonic waves.

Claims 3-5 are directed to the coupling medium composition.

The claims recite the following components: "at least on polysaccharide, a surface active substance, and water". The preferred polysaccharides are listed on page 6, second full paragraph. Polysaccharide has the accepted meaning (see Webster's II and Hawley's cited herein) of nine or more monosaccharides linked through glycosidic bonds such as starch, cellulose and glycogen and includes carbohydrates and phytocolloids. Applicants definition is broader than the accepted definition and clearly include disaccharides such as sucrose, saccharose and trehalose.

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The "surface active substance" has been characterized as preferably "non-toxic" and "biocompatible" (page 5, first full paragraph) and by preferred examples (page 6, second full paragraph) including lipids, Aerosol® OT, phospholipids, and glykolipids.

***Claim Rejections - 35 USC § 101***

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 1 provides for the use of a homogenized mixture, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

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9. Claims 2-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is dependent on claim 1 but contains the steps, "wherein a layer of the mixture is applied" and "said surfaces are pressed together". The phrase, "a surface of a transmitting respectively receiving transducer for traverse ultrasonic waves" is confusing and indefinite.

Claims 3-5 set forth a "mixture having a creamy consistency". Applicants do not specifically define the meaning of the terms "creamy consistency". It is unclear what are the metes and bounds of the compositions and how "creamy consistency" limits the claimed subject matter.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 3-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Haefele, US 3,427,382. Haefele (examples) discloses gel compositions, which read on the claimed compositions and would have been expected to function as an ultrasound coupling medium since the compositions otherwise read on the claimed compositions. Haefele (column 5, lines 15-18) discloses the thickening agents reduces the acute oral

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toxicity of the gels. The disclosed compositions are biocompatible as skin/hair compositions.

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchalter, US 4,002,221, in view of Larson et al, US 6,039,694. Buchalter (abstract, examples and claims) discloses gelled coupling agents for ultrasonic impulses. Hydroxyethylcellulose is a polysaccharide.

Buchalter differs from the claims in the further addition of a surfactant and the characterization that the medium is for transverse waves.

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Larson et al (item [56] on patent face and column 2, lines 40-46) cites Buchalter, 4,002,221, and characterizes fluids or thickened water-based gels typically used in medical ultrasound similarly described in Buchalter to include cellulose ethers and other germicidal and fungicidal, and surfactants.

These references are combinable because they teach ultrasound coupling agents. It would have been obvious to one of ordinary skilled in the art at the time of applicants' invention to employ a surfactants as an obvious conventional additive for medical ultrasound coupling mediums as taught and evidenced in the Larson et al reference.

The prior art and the instant application make do not show any difference in the transmission of transverse waves and longitudinal waves in the coupling medium. The skilled artisan would have reasonably expected the medium to transmit either wave energy if it is taught as a coupling medium.

The instant specification does not provide comparative examples or evidence in the prior art, which would provide unexpected results of the claimed coupling medium.

### ***Conclusion***

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Crotty et al, US 3,655,579, is cited as cumulative to Haefele for claims 3 and 5.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel S. Metzmaier whose telephone number is (703) 308-0451. The examiner can normally be reached on 9:00 AM to 5:30 PM.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Dawson can be reached on (703) 308-2340. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

  
Daniel S. Metzmaier  
Primary Examiner  
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DSM